

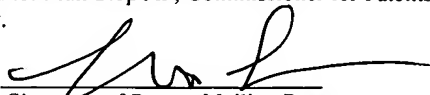


PATENT

Certificate of Mailing (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first-class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date set forth below.

Roberta Sherman
Name of Person Mailing Paper


Signature of Person Mailing Paper

July 07, 2006
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number: 10/781,453
Filing Date: February 18, 2004
Applicant(s): Eric Jason Stelnicki
Entitled: INFANT HEAD SLEEP GUARD AND METHOD OF USE
Examiner: Michael Safavi
Group Art Unit: 3673
Attorney Docket No.: 1027-2DIV

Mail Stop AF
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

In response to the Final Official Action mailed April 13, 2006, Applicant hereby requests review of the Final Rejection. No amendments are being filed with this request, and this request is being filed with a Notice of Appeal. The review is being requested for the reasons stated below.

REMARKS

1. CITED ART IS NOT IN A FIELD ANALOGOUS TO THAT OF THE PRESENT
INVENTION

On pages 2-6 of the April 13, 2006 Final Office Action ("the Final Office Action"), all of the pending claims were rejected under 35 U.S.C. §103, as obvious. The references mainly cited in the rejections include combinations of Inhat (U.S. Patent No. 3,588,914), El Hassen (U.S. Patent No. 4,646,367), Steffen (U.S. Patent No. 3,171,133) and Simpson (U.S. Patent No. 3,039,109). Additional rejections included combinations of the aforementioned patents, and further included Bridley (U.S. Patent 5,581,832) and Clavelle (5,675,840). The application of the references cited in the Office Action against Applicant's claimed invention is improper.

In order to properly rely on a reference under 35 U.S.C. §103, the reference must be analogous prior art, where "the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned," *In re Oetiker*, 977 F. 2d 1443 (Fed. Cir. 1992), as cited in MPEP §2141.01(a).

Both the specification and the claims of Applicant's invention clearly contemplate and provide an apparatus for treating a medical condition, namely, deformational plagiocephaly, on the head of an infant. The cited references of Inhat, Jr., El Hassen, Steffen and Simpson each disclose a protective device whose purpose it is to prevent injury from forceful impacts that may be experienced in sports or other potentially injurious activity. The Examiner concedes that these references "are directed to headwear with a concern for safety and protection of the head," as stated on Page 6 of the Final Office Action. However, the Examiner simply concludes, "as such, the applied art...falls within the scope of the instant invention," (Final Office Action, Page 6). The Examiner makes this erroneous conclusion even though Applicant makes no reference or disclosure towards preventing or protecting against injury, just as the cited references make no mention of providing therapeutic benefits, let alone treating a specific condition as in the case of the claims of the subject Application.

To further illustrate the impropriety of applying the cited art, the Bridley reference discloses, “an infant support which permits an infant to sleep on its side, but which is comfortable and not constricting,” and makes no mention whatsoever of providing a headgear element, let alone treating a medical condition. In addition, the Clavelle reference provides a skin heat shield system to protect a person receiving hair care treatments, which is clearly irrelevant to the field of Applicant’s endeavor.

The Examiner improperly characterizes the cited devices as inherently and obviously including support characteristics, when in fact the cited references specifically provide for protection against trauma, providing a safe sleeping position for an infant, and shielding against heat during hair treatment. As such, Applicant believes it to be improper to cite the above-mentioned references as they constitute non-analogous art that is irrelevant to the field of the endeavor and particular problem with which Applicant’s claimed invention is concerned, namely treating infant deformational plagiocephaly.

2. NO MOTIVATION TO MODIFY OR COMBINE REFERENCES IS PROVIDED

Moreover, the Office Action states in each of the rejections that it would have been obvious to make modifications to the cited references in order to obtain Applicant’s claimed invention. However, the requisite motivation to modify a reference must be derived from the applied prior art. Each of the Inhat, Jr., El Hassen, Steffen, Simpson, Bridley and Clavelle references, however, are silent as to any suggestion that such devices can be used to provide treatment for a medical condition, and are similarly silent as to providing support for the head of an infant. Furthermore, the Examiner has failed to explain how or why the various devices of Inhat, Jr., El Hassen, Steffen, Simpson, Bridley and Clavelle would be modified to provide for an infant positioning system for treatment of any medical condition, let alone deformational plagiocephaly. The Examiner has stated that, “one of ordinary skill in the headwear art would have taken the explicit protective headwear technology of any of El Hassen, Steffen, and Simpson to add a rear support (including toroidal support), to the rear of the protective headwear teaching of the Inhat headwear to further the protective area and protective capacity of the Inhat headwear,” (Final Office Action, Page 7). Primarily, as the toroidal cushions of Inhat are shaped to conform to the ears, there would be no

reason or motivation to move or add a toroidal cushion to the rear of the head, as obviously there are no ears located there. Furthermore, Applicant respectfully points out that positioning a toroidal cushion on the rear of the head would expose a portion of the skull through the opening in the cushion, thus subjecting the exposed portion to injury, which is exactly what the El Hassen '367, Steffen '133, and Simpson '109 references are focused on preventing.

On Page 7 of the Final Office Action, the Examiner further states, "the fact that Applicant has recognized another advantage *which would flow naturally from following the suggestion of the prior art* cannot be the basis for patentability..."(emphasis added). Applicant simply does not believe that the "protective sports headgear" of Inhat, the "tumbling cap" of El Hassen, the "protective helmet" of Steffen, the "safety helmet" for "crash landings or the like" of Simpson, the "skin heat shield system" of Clavelle, or the "infant sleeping device" of Bridley naturally suggest to one of skill in the art a treatment device for a medical condition such as deformational plagiocephaly.

Given the lack of factual support within Inhat, Jr., El Hassen, Steffen, Simpson, Bridley and Clavelle for the Examiner's asserted motivation to modify the various references, Applicant can only conclude that the Examiner has engaged in impermissible hindsight reconstruction based upon Applicant's teachings so as to arrive at the claimed invention. Furthermore, since the Examiner has failed to assert a proper motivation to modify the references cited, Applicant submits that the Examiner has failed to establish a prima facie basis to deny patentability to the claimed invention under 35 U.S.C. § 103 for lack of the requisite realistic motivation.

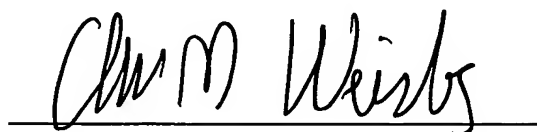
3. APPLICANT'S DISCUSSION REGARDING SPECIFIC REJECTIONS

The rejections contained in the Final Office Action mirror those contained in the Non-Final Office Action mailed on July 28, 2005. As such, for a discussion of specific rejections of the pending claims and the reasons supporting Applicant's belief of clear error on the Examiner's part, please refer to pages 8 through 13 of Applicant's response dated October 31, 2005, which was in response to the July 28, 2005 Non-Final Office Action.

For the reasons provided above as well as provided in the record, the claim rejections are believed to be improper and a result of clear error by the Examiner. Accordingly, pending Claims 9, 18, 23, and 26-28 are believed to be in condition for allowance, and reconsideration and allowance thereof is respectfully requested.

Respectfully submitted,

Date: July 07, 2006

A handwritten signature in black ink, appearing to read "Alan M. Weisberg", is written over a horizontal line.

Alan M. Weisberg
Reg. No.: 43,982
Attorney for Applicant(s)
Christopher & Weisberg, P.A.
200 East Las Olas Boulevard, Suite 2040
Fort Lauderdale, Florida 33301
Customer No. 31292
Tel: (954) 828-1488
Fax: (954) 828-9122

56501